Notice of Allowability	Application No.	Applicant(s)	
	09/901,572	OKUDA ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Amendment of November 15, 2004.*.

2. ☒ The allowed claim(s) is/are *claims 4, 5, 9-18, and 20*.

3. ☒ The drawings filed on *08 November 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *1-13-05* .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other *Claim Listing (Appendix I)*..

DETAILED ACTION

Status of the Claims

1. Claims 4, 5, 9-18, and 20 are pending in the present application. In the prior action, mailed on July 13, 2004, claims 4, 5, 9-18, and 20 were under consideration to the extent that they read on DNAs (and compositions thereof) comprising at least one substitution of an Asparaginine in an NXB N-glycosylation site for another amino acid. These claims were rejected. In the Response of November 15, 2004, the Applicant amended claims 5, 9, 10, and 12-16.

2. In view of the amendments made by the November 15 2004 Response, and the further amendments by Examiner's Amendment made below, claims 4, 5, 9-18, and 20 are found allowable.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Daniel A. Geselowitz on January 13, 2005.

The application has been amended as follows:

The claims have been amended to read as presented in the attached listing of the claims (Appendix I). The claims have been amended as indicated, and for the reasons stated, in the Interview Summary of January 13, 2005.

Claim Rejections - 35 USC § 101

4. **(Prior Rejection-Withdrawn)** Claims 4, 5, 10-18, and 20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. In view of the Amendment of claims 4 and 5 as indicated above (such that the claims now read on a Mycoplasma antigen), the rejection is withdrawn.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 5 and 12 were rejected in the prior action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on DNA molecules "derived from" prokaryotic cells. It was not clear what the term "derived from" was intended to convey. In view of the cancellation of this language from the claims, the rejection is withdrawn.

6. **(Prior Rejection- Withdrawn)** Claims 5 and 9 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims have been described above. The claims recites the limitation "wherein said DNA molecule derived from a prokaryotic cell."

There is no antecedent basis for this limitation in the claim. In view of the cancellation of this language from the claims, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 5 and 12 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims read on DNA molecules wherein "said DNA molecule derived from a prokaryotic cell is a DNA derived from Mycoplasma having the DNA sequence according to SEQ ID NO: 1 or SEQ ID NO: 2. In view of the amendments to the claims, and the indication by the Applicant on page 13 of the Response that the portion of the genome must include the full length of SEQ ID NO: 1 or 2, the rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 4, 5, 9-18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims were rejected because it was not clear whether claimed portion of a Mycoplasma genome is required to contain the altered NXB site. In view of the clarification that the portion must contain the modified NXB site on page 14 of the Response, the rejection is withdrawn.

9. **(Prior Rejection- Withdrawn)** Claims 5 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims have been described above. They read on any DNA from any Mycoplasma having the DNA sequence of SEQ ID NO: 1 or SEQ ID NO: 2.

In view of the amendment of the claims to require that the DNA comprises SEQ ID NO: 1 or 2, the rejection is withdrawn.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: As was indicated in the prior action, no art rejection is being made over claims directed to the modification of DNA encoding Mycoplasma proteins. This is because the art indicated that the Mycoplasma antigens were effective without such modification, (see, Saito et al. and Yoshida et al., cited in the prior action), thereby providing no suggestion or motivation to specifically modify Mycoplasma proteins for eukaryotic expression. However, the Applicant has demonstrated that such modification is required for Mycoplasma proteins to be effective vaccine antigens. See e.g., App. page 44. While the art indicates that certain benefits may be obtained by preventing N-glycosylation of prokaryotic cell proteins expressed in eukaryotic host cells (e.g. by NXB modification), these teachings are general in nature and do not suggest such modification of genes encoding the Mycoplasma antigens.

In view of the amendment of the claims such that all of the claims are limited to Mycoplasma antigens, all outstanding art rejections are withdrawn. .

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. Claims 4, 5, 9-18, and 20 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C. Housel 1/24/05

APPENDIX I

Listing of Claims

Claims 1-3: (cancelled).

Claim 4: An isolated DNA molecule, whose sequence comprises:

a portion of the genome of a prokaryotic cell, encoding an antigen, in which at least one DNA region encoding an NXB site, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during expression of the DNA molecule in a eukaryotic cell,

wherein said prokaryotic cell is Mycoplasma.

Claim 5: An isolated DNA molecule, whose sequence comprises:

a portion of the genome of a prokaryotic cell, encoding an antigen, in which at least one DNA region encoding an NXB site, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during expression of the DNA molecule in a eukaryotic cell,

wherein said prokaryotic cell is a Mycoplasma, and said portion of the genome includes the DNA sequence according to SEQ ID NO: 1 or SEQ ID NO: 2.

Claims 6-8: (cancelled).

Claim 9: A fused DNA molecule, wherein a DNA encoding a signal sequence has been ligated to the N-terminal end of a DNA molecule,

wherein the sequence of said DNA molecule comprises a portion of the genome of a prokaryotic cell encoding an antigen, in which at least one DNA region encoding an NXB site, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during expression of the DNA molecule in a eukaryotic cell

so that the fused DNA molecule may be expressed as a fusion protein,

wherein said portion of the genome of a prokaryotic cell has a DNA sequence described in SEQ ID N0: 1 or 2, and said signal sequence is a signal sequence from the gB of Marek's disease virus or a signal sequence from the gG of Rabies virus.

Claim 10: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding an NXB site, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein.

Claim 11: The recombinant virus according to claim 10, wherein the alteration that prevents N-glycosylation is at least one of the following:

(1) the alteration of the DNA sequence encoding asparagine (N) to a DNA sequence encoding an amino acid other than asparagine;

(2) the alteration of the DNA sequence encoding any amino acid (X) other than proline to a DNA sequence encoding proline, and

(3) the alteration of the DNA sequence encoding serine or threonine (B) to a DNA sequence encoding an amino acid other than serine or threonine.

Claim 12: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein,

wherein said prokaryotic cell is a Mycoplasma, and said portion of the genome includes the DNA sequence according to SEQ ID NO: 1 or SEQ ID NO: 2.

Claim 13: A recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a

prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein.

Claim 14: A recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA regions encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein,

wherein said signal sequence is a signal sequence from the gB gene of Marek's disease virus or a signal sequence from the gG gene of Rabies virus.

Claim 15: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline,

and B is serine or threonine, has been altered so that no N-glycosylation occurs during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein, or

a recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA regions encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein, wherein said virus is a poxvirus or a herpesvirus.

Claim 16: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein, or

a recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA regions encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein, wherein said virus is a virus that infects avians.

Claim 17: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein, or

a recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a

prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA regions encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein, wherein said virus is an avipoxvirus.

Claim 18: A recombinant virus that has integrated therein

(1) a DNA molecule whose sequence comprises a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA region encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs during the expression of the DNA molecule in a eukaryotic cell, or

(2) a fused DNA molecule in which a DNA encoding a signal sequence is ligated to the N-terminal end of said DNA molecule of (1) so that it may be expressed as a fusion protein, or

a recombinant virus that has integrated therein a fused DNA molecule, wherein a first DNA encoding a signal sequence that has been altered so that no N-glycosylation occurs in the protein encoded by said first DNA during the expression in a eukaryotic cell has been ligated to the N-terminal end of a second DNA molecule comprising a portion of the genome of a prokaryotic cell encoding an antigen, wherein said prokaryotic cell is Mycoplasma, in which at least one DNA regions encoding NXB, wherein N is asparagine, X is any amino acid other than proline, and B is serine or threonine, has been altered so that no N-glycosylation occurs

at said NXB site during the expression of said fused DNA molecule in a eukaryotic cell, so that it may be expressed as a fusion protein, wherein said virus is a Marek's disease virus type I, type II, or type III.

Claim 19: (cancelled).

Claim 20: A vaccine comprising the recombinant virus according to claim 10 or 13.